EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 532571**

Issued To: **Nox Medical**
Katrínartúni 2
Reykjavík
IS-105
Iceland

In respect of:

The design and manufacture of sleep diagnostic devices

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2008-08-28** Date: **2019-02-14** Expiry Date: **2023-08-27**

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 532571**
Date:	**2019-02-14**
Issued To:	**Nox Medical** **Katrínartúni 2** **Reykjavík** **IS-105** **Iceland**

Subcontractor:	**Service(s) supplied**
Jiangyin Sinbon No 288 Chengjiang Middle Road Economic and Development Zone Jiangyin City Jiangsu Province 214434 P.R. China	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 532571**
Date: **2019-02-14**
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Katrínartúni 2
Reykjavík
IS-105
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Date	Reference Number	Action
28 August 2008	7146275	First Issue
05 May 2010	7520233	Certificate reissue due to change of address from: Nox Medical, Impra Keldnaholti, Reykjavik, IS-112, Iceland to: Nox Medical, Vatnagordum 18, Reykjavik, IS-104, Iceland
23 November 2011	7718422	Certificate reissue due to change of scope to include design. Product Standard changed from 93/42/EEC, Annex V, Section 3.2 to 93/42/EEC, Annex II, Section 3.2.
05 February 2013	7946029	Certificate reissue due to change of company address from 'Vatnagordum 18, IS-104 Reykjavik' to 'Katrínartúni 2, IS-105 Reykjavík'
26 July 2013	7982981	Certificate Renewal
13 July 2018	8892229	Certificate Renewal Correction to sub-contractor address Jiangyin SINBON Electronics Co., Ltd
Current	7780268	Traceable to NB 0086.